



UNITED STATES PATENT AND TRADEMARK OFFICE

HL

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/669,281

09/23/2003

Robert W. Esmond

4012.0373-01000

6560

22852

7590

08/25/2004

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,281

Applicant(s)

ESMOND ET AL.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-19 and 21-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7&12/2003-4</u> . | 6) <input type="checkbox"/> Other: ____ |

Art Unit: 1614

DETAILED ACTION

Priority

1. This application discloses and claims only subject matter disclosed in prior Application No. 09/394712, filed 09/13/1999, and names an inventor or inventors named in the prior application. Accordingly, this application is a continuation. Acknowledgement is made of applicant's claim for domestic priorities under 35 U.S.C. 120.

Status of Application

2. Acknowledgement is made of preliminary amendment filed Jan. 09, 2004. Upon entering the amendment, the claims 1, 2, 7-8 and 13 are amended and the claims 3-6 and 20 are canceled.

3. The claims 1-2, 7-19 and 21-28 are pending and presented for the examination.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-2, 7-19 and 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

However, the claimed invention is enabled because complete etiology and pathogenesis of Alzheimer's disease is unknown and thus primary prevention is infeasible. As evidenced by applicant's own admission, the underlying mechanisms involved in the development of Alzheimer's disease are not completely understood and furthermore, more than one mechanisms are likely involved in said development, the complete prevention of Alzheimer's diseases is not enabled, see instant specification at page 2, lines 10-11.

Attention is directed to *In re Wands*, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's) at 547 the court recited eight factors:

1) *The nature of the invention:*

The instant invention is related to a method for the prevention of Alzheimer's disease using an effective amount of an agent selected from at least one member of the group of troglitazone, ciglitazone, pioglitazone, chromium and so on.

2) *The state of the prior art:*

As stated in the instant specification, the state of art recognizes that the underlying mechanisms involved in the development of Alzheimer's disease are not completely understood and furthermore, more than one mechanisms are likely involved in said development, see instant specification at page 2, lines 10-11. As evidenced by numerous documents available at the time of the invention

Art Unit: 1614

was made clearly indicated that there is no complete prevention or cure for the said disease, see PTO-892.

The art does not recognize or teach that no examples exist for the prevention of Alzheimer's disease.

3) *The relative skill of those in the art:*

The relative skill of those in the art is high.

4) *The predictability of the art:*

The high degree of unpredictability in the treatment of neurological disorders such as Alzheimer's disease is well known in the art. A slight change in the structure of the drug would drastically change its selectivity for the receptor and its inhibitory activity as evidenced by the structurally very similar compounds.

Furthermore, without complete understanding of pathogenesis or underlying mechanism of Alzheimer's disease, the outcome of the treatment is even more unpredictable.

5) *The breadth of the claims:*

Applicant's assertion that the inventive compounds, its composition would be useful for preventing Alzheimer's disorders does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability and the limited working examples.

6) *The amount of guidance/working examples:*

The specification only exemplifies test for regulating insulin signal transduction cascade that subsequently influencing NTP gene expression. The example fails to show any human or animal involvement. Furthermore, the

Art Unit: 1614

exemplified test does not show complete inhibition or prevention nor fat , see figure 1. Therefore, the specification has not enabled the prevention of occurrence or development of said Alzheimer's disease or the delay in the onset of said development.

7) *Quantitation of undue experimentation.*

Since insufficient teaching and guidance have been provided in the specification, one of ordinary skill in the art, even with high degree of skill, would not be able to use the composition as claimed without undue experimentation for the prevention of the occurrence of Alzheimer's disease.

The true fact of the state of the art in neurological or brain disorder therapy is expressed well, "The significance of particular drug treatment for modifying different aspects of biological activity cannot be predicted a-priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study " to determine the efficacy against preventing Alzheimer's diseases.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1614

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 7-19 and 21-28 are rejected under 35 U.S.C. 102(b) as being anticipated by instant application and the references cited therein(see pages 6-10).

The instant application disclosed the use of the claimed compounds(e.g. troglitazone, chromium or metabolized carbohydrate) in various treatments(e.g. diabetic mellitus) by stating numerous documents, for instance, US5468775, US5597832, US5478852, US5716975, or Eads et al(1996). Although the references are silent about the prophylactic use of said compounds in preventing Alzheimer's disease, the references teaching of administering said compounds to the subject in overlapping dosage amounts inherently possesses such protective utility as the claimed invention. Therefore, the admission of instant application and the references cited therein clearly anticipates the claimed invention.

Conclusion

8. No claim is allowed.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER



Vickie Kim
August 23, 2004
Art unit 1614